

SAFETY DATA SHEETS

This SDS packet was issued with item:

078804604

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078870458



MSDS: AK-Poly-Bac Ophthalmic Ointment

Manufacturer: Akorn
72-6 Veronica Ave
Somerset, N.J. 08873
Contact Telephone: 1-800-932-5676
Email: customer.service@akorn.com

Section 1 - IDENTIFICATION

TRADE NAME: AK-POLY-BAC (Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment, USP)
NDC # 17478-238-35

Description: Colorless to light yellowish translucent ointment

Composition	CAS#	TLV (mg/m ³)	PEL (mg/m ³)	%Content
Bacitracin Zinc, Sterile	1405-89-6	NE	NE	< 1
Polymyxin B Sulfate, Sterile	1405-20-5	NE	NE	< 1
White Petrolatum	8009-03-8	NE	NE	85
Mineral Oil	8042-47-5	5(mist)	5	14

Common name of active ingredients: Bacitracin Zinc & Polymyxin B Sulfate

Chemical Formula: N/A

Section 2 – HAZARDOUS INGREDIENTS

Principal Hazardous Ingredients: Bacitracin Zinc & Polymyxin B Sulfate
% Threshold Limit Value: NE
Carcinogenicity: NE
NTP- No
IARC- No
OSHA- No
NE= Not established
< = Greater Than
> = Less Than

Section 3 – PHYSICAL AND CHEMICAL CHARACTERISTICS

Physical State: Semi solid
Appearance: Colorless to light yellowish translucent ointment
Odor: Odorless
Boiling Point: NE **Vapor Density:** NE
Vapor Pressure (mm Hg): NE **Viscosity:** NE
Solubility in Water: Immiscible
Specific Gravity: NE **Volatile:** NE
Evaporation Rate: NE **Reactivity in Water:** NE
Latex Free: Yes **NE=**Not Established



MSDS: AK-Poly-Bac Ophthalmic Ointment

Section 4 – FIRE AND EXPLOSION HAZARD DATA

Flammable Properties: Flash Point: NE

Method: NE

Extinguisher Media: Alcohol foam, dry chemical and Carbon dioxide

Hazardous Products: Toxic fumes.

Fire Fighting Instructions: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

Section 5 – REACTIVITY DATA

Stability: Stable

Incompatibility: The product has no incompatibilities except those of water e. g. strong acids, bases, alkali metals, alkali hydrides.

Hazardous Decomposition Products: Emits SO_x , NO_x , and toxic fumes.

Hazardous Polymerization: Should not occur.

Conditions to Avoid: Extreme heat, sparks, open flame, oxidizers, strong acids and alkalies.

Section 6 – HEALTH HAZARDS

Potential Health Hazards:

1. **Eyes:** Use only specified ophthalmic ointment in eyes. Topical ointment could cause eye irritation. May also cause hypersensitivity in some individuals.
2. **Skin:** Non-toxic under standard application.
3. **Ingestion:** May cause irritation and hypersensitivity to some individuals. Ingestion of large quantities may induce gastric disturbances.
4. **Inhalation:** Not likely due to the physical state of the product.

Chronic Effects: May cause irritation and hyper-sensitivity. As with other antibiotic preparations, prolonged use may result in the overgrowth of non-susceptible organisms, including fungi. Appropriate measures should be taken if such situation occurs.

Chemical Listed as Carcinogen or Potential Carcinogen: Bacitracin Zinc & Polymyxin B Sulfate

National Toxicology Program: No

I.A.R.C Monographs: No

OSHA: No

OSHA Permissible Exposure Limit: NE

ACGIH Threshold Limit Value: NE

NE= Not established

Emergency and First Aid Procedures:

1. **Eyes:** Flush eyes with copious amounts of water for at least 15 minutes.
2. **Skin:** Wash with soap and water.
3. **Ingestion:** Induce vomiting. Do not give anything to an unconscious person.



MSDS: AK-Poly-Bac Ophthalmic Ointment

Section 7 – SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

Storage: Store product upright in original containers with the cap tightly closed at a controlled room temperature 20° – 25° C (68° – 77° F). Avoid physical damage and heat.

Neutralizing Chemical Agent: Not relevant

Steps to be taken in case material is released or spilled: Assure slippery conditions are nullified. Add dry sand or a suitable absorbent. Scoop up and remove. Dispose in accordance with federal, state and local regulations.

Waste Disposal Methods: Assure conformity with applicable disposal regulations. Dispose of absorbed material at approved incineration or chemical landfill waste disposal site.

Section 8 – PROTECTION INFORMATION

Engineering Controls: Personal involved in handling the raw material in compounding process should use adequate personal protective equipment, e. g. NIOSH approved respirator, goggles, gloves and protective clothing. Ensure training in the handling of chemical material and use of current Material Safety Data Sheets.

Airborne Exposure Limits: NE

Ventilation: Recommended

Skin Protection: Normal hygiene

Eye Protection: Normal hygiene

Respiratory Protection: General ventilation.

Section 9 – TOXICOLOGY INFORMATION

LD 50 (Acute oral toxicity of):	Bacitracin Zinc	Polymyxin B Sulfate
LD 50 rat, oral =	NE	NE
LD 50 rat, intravenous =	NE	NE
LD 50 rat, intramuscular =	NE	NE
LD 50 mouse, Oral =	NE	790 mg (base)/kg
LD 50 mouse, intravenous =	NE	5.4 mg/kg
Chronic Effects on Humans: NE		

Section 10 – ECOLOGICAL INFORMATION

Ecotoxicity: Not established

BOD₅ and COD: Not available

Environmental fate information: NE

Other Precautions: None

Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this MSDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this MSDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.



**SDS: Neomycin and Polymyxin B Sulfates,
Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment, USP**

SAFETY DATA SHEET

1. Identification

Product Identifier: Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment, USP

Synonyms: Neomycin B Sulfates, Polymyxin B Sulfates

National Drug Code (NDC): 17478-719-35

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Neomycin Sulfate	1405-10-3	Neomycin B Sulfate	$C_{23}H_{46}N_6O_{13} \cdot 3H_2SO_4$	908.89	0.35%
Polymyxin B Sulfate	1405-20-5	Polymyxin B Sulfate	$C_{43}H_{82}N_{16}O_{12} \cdot xH_2O_4S$	1701.97	equal to 10,000 Polymyxin B units
Bacitracin Zinc	1405-89-6	Bacitracins, zinc complex,	$C_{66}H_{101}N_{17}O_{16}SZn$	1486	400 units of Bacitracin
Hydrocortisone	50-23-7	Cortisol	$C_{21}H_{30}O_5$	362.47	10 1%

* The formula also contains White Petrolatum q.s.



**SDS: Neomycin and Polymyxin B Sulfates,
Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment, USP**

4. First Aid Measures

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders:

Use personal protective equipment (see section 8).

Signs and Symptoms:

Not determined. See package insert for more information.

**Medical Conditions Aggravated
by Exposure:**

Anaphylactic cross-reactions may occur for corticosteroids and antibiotics including kanamycin, paromomycin, streptomycin and possibly gentamicin. This medication is contraindicated for patients with herpes simplex, vaccinia and varicella infections. As with other anti-microbial preparations, prolonged use may result in overgrowth of nonsusceptible organisms including fungi. Preexisting conjunctival or systemic fungal infections may be aggravated. Appropriate measures should be taken if this occurs. Ophthalmic ointments may retard corneal healing.

Notes to Physician:

Treat supportively and symptomatically.



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5. Firefighting Measures

Suitable Extinguishing Media: Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials. Use water spray to keep fire-exposed containers cool

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: Emits SO_x, NO_x, and toxic fumes.

Other Specific Hazards: Not determined.

**Special Protective Equipment/
Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State, and Local regulations.

Environmental Precautions: No data available.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage,
Including Any Incompatibilities:** Store product upright in original containers with the cap tightly closed at a controlled room temperature 15°C – 30°C (59°F – 86°F). KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Specific End Use: Pharmaceuticals.



**SDS: Neomycin and Polymyxin B Sulfates,
Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment, USP**

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Neomycin Sulfate	100 mg/m ³ TWA
Polymyxin B Sulfate	Not established.
Bacitracin Zinc	Not established.
Hydrocortisone	0.02 mg/m ³ TWA

Engineering Controls:

Engineering controls should be used as the primary means to control exposures.

Respiratory Protection:

Warning: Do not use air purifying respirators in oxygen depleted environments. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection:

Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection:

Not required for the normal use of this product. Wear chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection:

Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:

Smooth, unctuous cloudy white ointment.

Odor:

No data available.

Odor Threshold:

No data available.

pH:

No data available.

Melting Point:

No data available.

Freezing Point:

No data available.

Boiling Point:

No data available.

Flash Point:

No data available.

Evaporation Rate:

No data available.

Flammability (solid, gas):

No data available.

Flammability Limit - Lower:

No data available.



SDS: Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment, USP

Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Immiscible in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid (e.g., static discharge, shock, or vibration): Extreme heat or cold.

Incompatible Materials: This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

Hazardous Decomposition Products: No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	No data available.
Ingestion:	No data available.
Skin Contact:	No data available.
Eye Contact:	No data available.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity:

Compound	Species	Route	Type	Dose
Bacitracin Zinc	Guinea Pig	Oral	LD ₅₀	2,000 mg/kg
Neomycin Sulfate	Rat	Oral	LD ₅₀	2,750 mg/kg
Polymyxin B Sulfate	Mouse	Oral	LD ₅₀	790 mg/kg
Polymyxin B Sulfate	Mouse	Intraperitoneal	LD ₅₀	20.5 mg/kg
Polymyxin B Sulfate	Mouse	Intravenous	LD ₅₀	5.4 mg/kg
Polymyxin B Sulfate	Mouse	Subcutaneous	LD ₅₀	59.5 mg/kg
Hydrocortisone	Rat	Intraperitoneal	LD ₅₀	150 mg/kg
Hydrocortisone	Rat	Subcutaneous	LD ₅₀	449 mg/kg



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Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment, USP**

Acute Toxicity – Dermal:	No data available.
Acute Toxicity – Inhalation:	No data available.
Corrosivity:	No data available.
Dermal Irritation:	No data available.
Eye Irritation:	No data available.
Sensitization:	No data available.
Toxicokinetics/Metabolism:	No data available.
Target Organ Effects:	No data available.
Reproductive Effects:	No data available.
Carcinogenicity:	No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.
Aspiration Hazard: Based on available data, the classification criteria are not met.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.



**SDS: Neomycin and Polymyxin B Sulfates,
Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment, USP**

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA): Not listed.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

California Proposition 65: Not listed.

16. Other Information

Not made with natural rubber latex.

Revision Date: 05/06/2015

Revision Number: 1

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SDS: AK-Poly-Bac™
(bacitracin zinc and polymyxin B sulfate
ophthalmic ointment, USP)

SAFETY DATA SHEET

1. Identification

Product Identifier: AK-Poly-Bac™ (bacitracin zinc and polymyxin B sulfate ophthalmic ointment, USP)

Synonyms: AK-Poly-Bac™; Bacitracin Zinc ((4R)-4-[(2S)-2-[(2-[(1S)-1-amino-2-methylbutyl]-4,5-dihydro-1,3-thiazol-5-yl]formamido)-4-methylpentanamido]-4-[(1S)-1-[(3S,6R,9S,12R,15S,18R,21S)-18-(3-aminopropyl)-12-benzyl-15-(butan-2-yl)-3-(carbamoylmethyl)-6-(carboxymethyl)-9-(1H-imidazol-5-ylmethyl)-2,5,8,11,14,17,20-hepta-1,4,7,10,13,16,19-heptaazacyclopentacosan-21-yl]carbamoyl]-2-methylbutyl]carbamoyl]butanoic acid zinc salt) and Polymyxin B Sulfate (N-[4-amino-1-[[1-[[4-amino-1-oxo-1-[[6,9,18-tris(2-aminoethyl)-15-benzyl-3-(1-hydroxyethyl)-12-(2-methylpropyl)-2,5,8,11,14,17,20-hepta-1,4,7,10,13,16,19-heptazacyclotricos-21-yl]amino]butan-2-yl]amino]-3-hydroxy-1-oxobutan-2-yl]amino]-1-oxobutan-2-yl]-6-methyloctanamide sulfate salt) Ophthalmic Ointment USP.

National Drug Code (NDC): 17478-238-35

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

SDS: AK-Poly-Bac™
(bacitracin zinc and polymyxin B sulfate
ophthalmic ointment, USP)

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
(4R)-4-[(2S)-2-[(2-[(1S)-1-amino-2-methylbutyl]-4,5-dihydro-1,3-thiazol-5-yl]formamido)-4-methylpentanamido]-4-[(1S)-1-[(3S,6R,9S,12R,15S,18R,21S)-18-(3-aminopropyl)-12-benzyl-15-(butan-2-yl)-3-(carbamoylmethyl)-6-(carboxymethyl)-9-(1H-imidazol-5-ylmethyl)-2,5,8,11,14,17,20-heptaaxo-1,4,7,10,13,16,19-heptaazacyclopentacosan-21-yl]carbamoyl]-2-methylbutyl]carbamoyl]butanoic acid zinc salt	1405-89-6	Bacitracin zinc salt, bacitracin zinc complex, bactiferm	$C_{66}H_{101}N_{17}O_{16}SZn$	1,486.07	<1
N-[4-amino-1-[[1-[[4-amino-1-oxo-1-[[6,9,18-tris(2-aminoethyl)-15-benzyl-3-(1-hydroxyethyl)-12-(2-methylpropyl)-2,5,8,11,14,17,20-heptaaxo-1,4,7,10,13,16,19-heptazacyclotricos-21-yl]amino]butan-2-yl]amino]-3-hydroxy-1-oxobutan-2-yl]amino]-1-oxobutan-2-yl]-6-methyloctanamide sulfate salt	1405-20-5	Polymyxin B Sulfate	$C_{55}H_{96}N_{16}O_{13} \cdot 2H_2SO_4$	1,385.61	<1

*The formula also contains White Petrolatum and Mineral Oil.

4. First Aid Measures

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as



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necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders:

Use personal protective equipment (see section 8).

Signs and Symptoms:

Vomiting, diarrhea, and abdominal pain if ingested. May cause irritation. May cause hypersensitivity.

**Medical Conditions Aggravated
by Exposure:**

No data available.

Notes to Physician:

Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:

Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media:

Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:

These products include carbon oxides, nitrogen oxides, sulfur oxides, and zinc/zinc oxides.

Other Specific Hazards:

Closed containers may explode from the heat of fire.

**Special Protective Equipment/
Precautions for Firefighters:**

Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions:

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment:

For personal protection see section 8.

Methods for Cleaning Up:

Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions:

Contain material and prevent release to basements, confined spaces, waterways or soil.



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ophthalmic ointment, USP)

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information. Store away from oxidizers, acids and bases.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Bacitracin zinc salt	Not established.
Polymyxin B Sulfate	Not established.
Mineral oil	OSHA PEL 5 mg/m ³ (Mist)

Engineering Controls: Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic



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ophthalmic ointment, USP)

non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection:

Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Semi-solid/Colorless to light yellowish translucent.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	No data available.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Immiscible in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Oxidizers acids and bases.
Hazardous Decomposition Products:	No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	May be harmful if swallowed.



SDS: AK-Poly-Bac™
(bacitracin zinc and polymyxin B sulfate
ophthalmic ointment, USP)

Skin Contact: May be harmful if absorbed through the skin. May cause skin irritation.

Eye Contact: May cause eye irritation.

**Symptoms Related to the Physical,
Chemical and Toxicological
Characteristics:**

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of
Exposure:**

No data available.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Polymyxin B Sulfate	Mouse	Oral	LD ₅₀	790 mg/kg
Bacitracin Zinc	Rat	Oral	LD ₅₀	2,000 mg/kg
Petrolatum	Rat	Oral	LD ₅₀	5,000 mg/kg
Mineral Oil	Rat	Oral	LD ₅₀	5,000 mg/kg

Acute Toxicity – Dermal: No data available.

Acute Toxicity – Inhalation: No data available.

Corrosivity: No data available.

Dermal Irritation: No data available.

Eye Irritation: No data available.

Sensitization: No data available.

Toxicokinetics/Metabolism: No data available.

Target Organ Effects: No data available.

Reproductive Effects: No data available.

Carcinogenicity: No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on
Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health
Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.

Aspiration Hazard: No data available.

12. **Ecological Information**

Ecotoxicity

Aquatic:

Compound	Species	Test Type	Dose
Bacitracin Zinc Salt	Daphnia magna	EC ₅₀	30.48 mg/l (48 hours)

Terrestrial: No data available.

Persistence and Degradability: No data available.



SDS: AK-Poly-Bac™
(bacitracin zinc and polymyxin B sulfate
ophthalmic ointment, USP)

Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	Harmful to aquatic life.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA):	This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.
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CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
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SARA 313:	Bacitracin zinc salt.
SARA 302:	Not listed.

State Regulations

Massachusetts:	Not listed.
New Jersey:	Polymyxin B Sulfate; Bacitracin Zinc Salt
Pennsylvania:	Polymyxin B Sulfate; Bacitracin Zinc Salt
California Proposition 65:	Not listed.



SDS: AK-Poly-Bac™
(bacitracin zinc and polymyxin B sulfate
ophthalmic ointment, USP)

16. Other Information

Not made with natural rubber latex.

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Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.



SDS: AK-Poly-Bac™
(bacitracin zinc and polymyxin B sulfate
ophthalmic ointment, USP)

SAFETY DATA SHEET

1. Identification

Product Identifier: AK-Poly-Bac™ (bacitracin zinc and polymyxin B sulfate ophthalmic ointment, USP)

Synonyms: AK-Poly-Bac™; Bacitracin Zinc ((4R)-4-[(2S)-2-[(2-[(1S)-1-amino-2-methylbutyl]-4,5-dihydro-1,3-thiazol-5-yl]formamido)-4-methylpentanamido]-4-[(1S)-1-[(3S,6R,9S,12R,15S,18R,21S)-18-(3-aminopropyl)-12-benzyl-15-(butan-2-yl)-3-(carbamoylmethyl)-6-(carboxymethyl)-9-(1H-imidazol-5-ylmethyl)-2,5,8,11,14,17,20-hepta-1,4,7,10,13,16,19-heptaazacyclopentacosan-21-yl]carbamoyl]-2-methylbutyl]carbamoyl]butanoic acid zinc salt) and Polymyxin B Sulfate (N-[4-amino-1-[[1-[[4-amino-1-oxo-1-[[6,9,18-tris(2-aminoethyl)-15-benzyl-3-(1-hydroxyethyl)-12-(2-methylpropyl)-2,5,8,11,14,17,20-hepta-1,4,7,10,13,16,19-heptazacyclotricos-21-yl]amino]butan-2-yl]amino]-3-hydroxy-1-oxobutan-2-yl]amino]-1-oxobutan-2-yl]-6-methyloctanamide sulfate salt) Ophthalmic Ointment USP.

National Drug Code (NDC): 17478-238-35

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

SDS: AK-Poly-Bac™
(bacitracin zinc and polymyxin B sulfate
ophthalmic ointment, USP)

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
(4R)-4-[(2S)-2-[(2-[(1S)-1-amino-2-methylbutyl]-4,5-dihydro-1,3-thiazol-5-yl]formamido)-4-methylpentanamido]-4-[[[(1S)-1-[(3S,6R,9S,12R,15S,18R,21S)-18-(3-aminopropyl)-12-benzyl-15-(butan-2-yl)-3-(carbamoylmethyl)-6-(carboxymethyl)-9-(1H-imidazol-5-ylmethyl)-2,5,8,11,14,17,20-heptaaxo-1,4,7,10,13,16,19-heptaazacyclopentacosan-21-yl]carbamoyl]-2-methylbutyl]carbamoyl]butanoic acid zinc salt	1405-89-6	Bacitracin zinc salt, bacitracin zinc complex, bactiferm	$C_{66}H_{101}N_{17}O_{16}SZn$	1,486.07	<1
N-[4-amino-1-[[1-[[4-amino-1-oxo-1-[[6,9,18-tris(2-aminoethyl)-15-benzyl-3-(1-hydroxyethyl)-12-(2-methylpropyl)-2,5,8,11,14,17,20-heptaaxo-1,4,7,10,13,16,19-heptazacyclotricos-21-yl]amino]butan-2-yl]amino]-3-hydroxy-1-oxobutan-2-yl]amino]-1-oxobutan-2-yl]-6-methyloctanamide sulfate salt	1405-20-5	Polymyxin B Sulfate	$C_{55}H_{96}N_{16}O_{13} \cdot 2H_2SO_4$	1,385.61	<1

*The formula also contains White Petrolatum and Mineral Oil.

4. First Aid Measures

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as



SDS: AK-Poly-Bac™
(bacitracin zinc and polymyxin B sulfate
ophthalmic ointment, USP)

necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders:

Use personal protective equipment (see section 8).

Signs and Symptoms:

Vomiting, diarrhea, and abdominal pain if ingested. May cause irritation. May cause hypersensitivity.

**Medical Conditions Aggravated
by Exposure:**

No data available.

Notes to Physician:

Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:

Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media:

Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:

These products include carbon oxides, nitrogen oxides, sulfur oxides, and zinc/zinc oxides.

Other Specific Hazards:

Closed containers may explode from the heat of fire.

**Special Protective Equipment/
Precautions for Firefighters:**

Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions:

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment:

For personal protection see section 8.

Methods for Cleaning Up:

Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions:

Contain material and prevent release to basements, confined spaces, waterways or soil.



SDS: AK-Poly-Bac™
(bacitracin zinc and polymyxin B sulfate
ophthalmic ointment, USP)

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information. Store away from oxidizers, acids and bases.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Bacitracin zinc salt	Not established.
Polymyxin B Sulfate	Not established.
Mineral oil	OSHA PEL 5 mg/m ³ (Mist)

Engineering Controls: Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic



SDS: AK-Poly-Bac™
(bacitracin zinc and polymyxin B sulfate
ophthalmic ointment, USP)

non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection:

Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Semi-solid/Colorless to light yellowish translucent.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	No data available.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Immiscible in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Oxidizers acids and bases.
Hazardous Decomposition Products:	No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	May be harmful if swallowed.



SDS: AK-Poly-Bac™
(bacitracin zinc and polymyxin B sulfate
ophthalmic ointment, USP)

Skin Contact: May be harmful if absorbed through the skin. May cause skin irritation.

Eye Contact: May cause eye irritation.

**Symptoms Related to the Physical,
Chemical and Toxicological
Characteristics:**

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of
Exposure:**

No data available.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Polymyxin B Sulfate	Mouse	Oral	LD ₅₀	790 mg/kg
Bacitracin Zinc	Rat	Oral	LD ₅₀	2,000 mg/kg
Petrolatum	Rat	Oral	LD ₅₀	5,000 mg/kg
Mineral Oil	Rat	Oral	LD ₅₀	5,000 mg/kg

Acute Toxicity – Dermal: No data available.

Acute Toxicity – Inhalation: No data available.

Corrosivity: No data available.

Dermal Irritation: No data available.

Eye Irritation: No data available.

Sensitization: No data available.

Toxicokinetics/Metabolism: No data available.

Target Organ Effects: No data available.

Reproductive Effects: No data available.

Carcinogenicity: No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on
Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health
Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.

Aspiration Hazard: No data available.

12. **Ecological Information**

Ecotoxicity

Aquatic:

Compound	Species	Test Type	Dose
Bacitracin Zinc Salt	Daphnia magna	EC ₅₀	30.48 mg/l (48 hours)

Terrestrial: No data available.

Persistence and Degradability: No data available.



SDS: AK-Poly-Bac™
(bacitracin zinc and polymyxin B sulfate
ophthalmic ointment, USP)

Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	Harmful to aquatic life.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA):	This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.
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CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
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SARA 313:	Bacitracin zinc salt.
SARA 302:	Not listed.

State Regulations

Massachusetts:	Not listed.
New Jersey:	Polymyxin B Sulfate; Bacitracin Zinc Salt
Pennsylvania:	Polymyxin B Sulfate; Bacitracin Zinc Salt
California Proposition 65:	Not listed.



SDS: AK-Poly-Bac™
(bacitracin zinc and polymyxin B sulfate
ophthalmic ointment, USP)

16. Other Information

Not made with natural rubber latex.

Revision Date: 06/15/2015

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